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IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

LUCIA PACCIONE,	:	**CIVIL ACTION NO.** 03-6268
Plaintiff	:	**FILED UNDER SEAL**
v.	:	**JURY TRIAL DEMANDED**
CEPHALON, INC.,	:	
Defendant.	:	

FILED
NOV 14 2003
MICHAEL E. KUNZ, Clerk
By _____ Dep. Clerk

COMPLAINT

The United States of America *ex rel.* Lucia Paccione state as follows for their Complaint against Cephalon, Inc. (hereinafter referred to as "Cephalon"):

I. NATURE OF THE CASE

1. This is an action by the United States of America and Relator/Plaintiff Lucia Paccione (hereinafter "Paccione") against Cephalon to redress violations of the False Claims Act 31 U.S.C. §§ 3729-3730.

2. Defendant Cephalon, a Delaware corporation, is a research-based, global pharmaceutical company, with its principal place of business located at 145 Brandywine Parkway, West Chester, PA 19380.

3. From in or about September 1994 to January 14, 2003, Plaintiff Paccione was employed by Cephalon as a Medical Sales Specialist, who was responsible for the marketing of Cephalon pharmaceutical products in the Philadelphia and New Jersey areas.

II. JURISDICTION AND VENUE

4. This is a civil action arising under the laws of the United States to redress violations of 31 U.S.C. §§3729-3730. This court has jurisdiction over the subject matter of this action: (i) pursuant to 31 U.S.C. §3732, which specifically confers jurisdiction on this Court for actions

brought pursuant to 31 U.S.C. §§3729 and 3730; (ii) pursuant to 28 U.S.C. §1331, which confers federal subject matter jurisdiction; and (iii) pursuant to 28 U.S.C. §1345, because the United States is a plaintiff.

5. This suit is not based upon prior public disclosures of allegations or transactions in a criminal, civil, or administrative hearing, lawsuit or investigation or in a Government Accounting Office or Auditor General's report, hearing, audit, or investigation, or from the news media.

6. To the extent that there has been a public disclosure unknown to Paccione, Paccione is an original source under 31 U.S.C. §3730 (e)(4), 740 ILCS 175/4(e)(4), and other state whistleblower statutes. She has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the government before filing a *qui tam* action based on the information.

7. Plaintiff Paccione is concurrently providing to the Attorney General of the United States and to the United States Attorney for the Eastern District of Pennsylvania a statement summarizing known material evidence and information related to this Complaint, in accordance with the provisions of 31 U.S.C. §3730(b)(2). This disclosure statement is supported by material evidence.

8. This court has jurisdiction over Cephalon under 31 U.S.C. §3732(a) because Cephalon can be found in, is authorized to transact business in, and is now transacting business in this District. In addition, acts proscribed by 31 U.S.C. §3729 have occurred in this District.

9. Venue is proper in the Eastern District of Pennsylvania and (c) because Cephalon conducts business in this District and, upon information and belief, the acts giving rise to this action occurred within this District.

III. PARTIES

10. The United States of America is the plaintiff for whom recovery is sought for false and fraudulent claims submitted to federally funded government programs.

11. Plaintiff and relator Lucia Paccione is a citizen and resident of the Commonwealth of Pennsylvania. She brings this action on her own behalf and on behalf of the government pursuant to 31 U.S.C. §3730(b)(1).

12. Defendant Cephalon, a Delaware corporation, is a research-based, global pharmaceutical company, with its principal place of business located at 145 Brandywine Parkway, West Chester, PA 19380.

IV. BACKGROUND

Cephalon Sales Organization

13. At all times relevant to this action, Defendant Cephalon maintained sales and sales support field forces that were divided into two sales divisions, the Central Nervous System Division ("CNS") and the Pain Division. The CNS Division currently markets Provigil and Gabitril. The Pain division markets Actiq.

14. Both Sales Divisions are divided into geographic regions throughout the country. Each Sales Division employs sales representatives who report to a District Manager for that Division. The District Managers then report to a Regional Manager for that Division. The Regional Managers then report to the National Sales Director.

15. For the past 81/2 years Lucy Paccione worked in the CNS Northeast Region as a medical sales representative, area trainer, and an institutional representative. During that time, she marketed Stadol (a co-marketing agreement with BMS), ITB (Medtronics), Gabitril (a co-

marketing agreement Abbott Pharmaceuticals, and Provigil. Paccione had responsibility for pharmaceutical sales in Philadelphia and New Jersey.

16. When Paccione first started with Cephalon in 1994, there were only twenty-seven sales representatives. She was one of only four of the original twenty-seven Cephalon sales representatives that were still employed by Cephalon when she was terminated in 2003. Since 1994, Paccione has seen the number of sales representatives grow to over 250. Because she was one of the first sales representatives hired by Cephalon, she is intimately aware of Cephalon's various marketing initiatives and the manner in which the marketing strategies have progressed over the years in both the CNS Division and the Pain Division. The pharmaceutical industry is highly regulated by the Food and Drug Administration ("FDA").

FDA Requirements For Drug Advertising and Labeling Information

17. The pharmaceutical industry is highly regulated by the Food and Drug Administration ("FDA").

18. Pursuant to the Food, Drug and Cosmetics Act, 21 U.S.C. §§ 301 *et seq.*, the FDA strictly regulates the content of consumer and physician based advertising, direct to physician product promotion, and drug labeling information used by pharmaceutical companies in promoting and selling FDA approved prescription drugs.

19. Under 21 C.F.R. § 202.1(k)(2), any brochures, handouts, slide shows or other such promotional materials aimed at physicians are deemed to be "product labeling" and is regulated as such.

20. Under relevant FDA regulations, product labeling must be pre-approved by the FDA and conform to very exacting requirements concerning, *inter alia*, drug interactions, indicated uses and claims concerning competing products. *See* 21 C.F.R. § 201.57.

21. All claims made in any labeling material must be truthful, not misleading and represent a fair balance of the information presented.

22. Any presentations, promotions, or marketing to physicians for products for use other than that approved for labeling purposes by the FDA is considered "off label" marketing and is thus prohibited by FDA regulation.

23. Any failure to fairly and accurately represent the required information about a prescription drug is considered misbranding and is a false and fraudulent statement as a matter of law. *See* 21 U.S.C. §§ 331(a) and (b), 352(a), (f) and (n); 21 C.F.R. § 201.57.

24. Pharmaceutical promotional and marketing materials and presentations lacking in fair balance or that are otherwise false or misleading violate the Food Drug and Cosmetics Act, 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated hereunder. Such violations exist where promotional and marketing materials and presentations for an FDA approved drug:

a. Minimize, understate or misrepresent the risks, contra-indications and complications associated with that drug;

b. Overstate or misrepresent the risks, contra-indications and complications associated with any competing drugs;

c. Reference "off label" uses of the drug for which it was not an approved indication by the FDA, or expressly or implicitly promote unapproved uses and dosing regimens for which the drug is not indicated;

d. Make comparative claims about the drug that have not been demonstrated by substantial evidence, such as comparisons with competing drugs and/or drug indications of patient usage, warnings and safety claims including side effects, physician preference, or

e. are otherwise false, misleading or lacking in fair balance in the presentation of information about the drug being marketed or any competing drug.

V. CEPHALON'S FALSE CLAIMS SCHEMES

25. Cephalon currently markets Provigil, Gabitril, and Actiq. The FDA has approved each of these medications only for the treatment of specific medical conditions.

26. In order to expand the market penetration of these drugs, Cephalon has engaged in a pattern of marketing each of these medications for "off-label" uses not approved by the FDA.

27. In order to effectuate its off label marketing program Cephalon has engaged in a scheme to make false representations as to the efficacy of certain of its medications.

28. The FDA has approved Gabitril as an adjunctive therapy in the ***treatment of partial seizures*** for adults and children twelve years and older. The FDA has not approved Gabtiril for any other medical purpose.

29. Because Gabitril has been approved for the treatment of partial seizures related to epilepsy, the physicians who would use this medication for its FDA approved purpose are neurologists and epileptologists. Yet Cephalon has improperly targeted psychiatrists and pain clinics as the primary markets for Gabitril because Cephalon believes that a much larger market exists for Gabitril as a treatment for anxiety , mood disorder, and pain.

30. The FDA has approved Actiq for the management of breakthrough ***cancer pain*** in patients with malignancy ***who is already receiving and who are tolerant to opiod therapy for their underlying persistent cancer pain.***

31. Because Actiq has been approved only for the treatment of breakthrough cancer pain in patients who are already receiving opiods for an underlying cancer, the physicians who

would primarily use Actiq for its FDA approved purpose are oncologists and pain specialists who are knowledgeable of and skilled in the use of schedule II opiods to treat cancer pain. Actiq has been marketed for approximately two years. Because the first year sales for Actiq, when Cephalon was being marketed to oncologists, were disappointing, Cephalon changed its marketing focus away from oncologists to physicians who do not treat cancer, but who do have patients experiencing severe pain.

32. Cephalon is now intensely marketing Actiq in the fields of physical rehabilitation, as well as targeting neurologist who treat severe headaches and even primary care physicians. This is particularly inappropriate because Actiq is a schedule two controlled substance that has significant side effects and that has not been approved for any of these "off-label" purposes.

33. Cephalon's off-label marketing campaign for Gabitril and Actiq include training its pharmaceutical representatives to make false statements concerning the efficacy of these medications.

34. All of Cephalon's "off-label" promotional activities constituted false and fraudulent statements as a matter of law under the Food, Drug, and Cosmetics Act, 21 U.S.C. section 331(a) and (b), 352(a) and (f) and regulations promulgated by the FDA to implement that Act.

35. Cephalon knew and intended that its "off-label" promotional campaign would improperly increase the submission of prescriptions for Gabitril, and for uses for which the drugs had not been FDA approved and in some cases for uses that were completely untested, including those prescriptions reimbursed by the Medicare and Medicaid programs.

36. Absent Cephalon's unapproved, illegal off-label marketing and its false statements concerning those medications, physicians would not have believed that it was medically prudent or necessary to write so many prescriptions for Gabitril or Actiq.

37. Cephalon's off-label marketing programs have been extremely successful leading to the submission of claims to the Medicare and Medicaid programs for medically unnecessary and imprudent prescriptions which otherwise would not have been paid by Medicare and Medicaid.

Cephalon's Illegal Promotion Of Gabitril

38. In August of 1999, Abbott Laboratories owned the rights to Gabitril. At that time Cephalon entered into an agreement with Abbott whereby Cephalon agreed to co-market Gabitril, along with Abbott, as a treatment for partial seizures related to epilepsy.

39. Cephalon began co-promoting Gabitril in August of 1999.

40. Cephalon informed its sales force that Abbott intended to do further studies on Gabitril for its potential use as a treatment for anxiety, mood disorder, and pain.

41. Because the FDA approved use of Gabitril was of such a limited nature, Cephalon gradually embarked upon an increasingly more aggressive "off-label" marketing program. Cephalon first began its of-label promotions for Gabitril by attempting to penetrate the "pain market".

42. Cephalon specifically targeted off-label promotions to the pain clinics where Cephalon sales representatives were instructed to promote Gabitril off-label as an alternative to benzodiazepine. This off-label promotion campaign was in effect by the second half of 2000.

43. In the first quarter of 2001, Cephalon purchased the rights for Gabitril from Abbott. Cephalon's off-label promotions with pain clinics had increased sales beyond the narrow market approved by the FDA but Cephalon realized that an even larger potential market for Gabitril existed in its potential use for depression, mood disorder and anxiety.

44. In 2001, Cephalon therefore embarked upon an even more aggressive off-label promotion campaign to market Gabitril to psychiatrists even though psychiatrists had no known use for the FDA approved purpose of Gabitril.

45. The sales representatives were told to use visual aids demonstrating what Cephalon management referred to as the "science" of Gabitril, i.e., the manner in which Gabitril functioned to control partial seizures related to epilepsy (its FDA approved use).

46. Gabitril is a selective GABA reuptake inhibitor. The precise mechanism of action is unknown; however, it is believed to enhance the activity of GABA, the major inhibitory neurotransmitter in the central nervous system. The visual aids used by the Cephalon sales representatives therefore demonstrated Gabitril's impact upon GABA.

47. The sales representatives were instructed to use the visual aids to discuss the "science" of Gabitril with the psychiatrists in order to explain how Gabitril could be used to treat anxiety, mood disorder, and pain.

48. The visual aids that the sales representatives were instructed to use with psychiatrists make no reference to pain, mood disorder, or anxiety. Cephalon reasons that because GABA directly affects anxiety, mood disorder, and pain, and, because Gabitril impacts upon GABA, Gabitril should be effective in treating all these illnesses.

49. However, as Cephalon well knows, the FDA has not approved Gabitril for any of these purposes and it is illegal for Cephalon to promote or market Gabitril for such "off-label" uses. In fact, there have been ***no FDA approved studies*** performed on Gabitril to determine its efficacy in the treatment of anxiety, mood disorder, or pain.

50. Thus Cephalon itself, without FDA approval or any empirical data of any type to support its claims, has determined that Gabitril should be marketed to treat anxiety, mood disorder, and pain.

51. The sales representatives have no basis to promote Gabitril in such discussions with physicians. Even if Gabitril were being actively tested for such purposes, the sales representatives

would not be authorized by the FDA to promote Gabitril for such purposes. Moreover, the sales representatives are not even remotely qualified or trained to persuade physicians that Gabitril may be effective in the treatment of anxiety, mood disorder, or pain. In fact, Cephalon sales representatives have no reason to call upon psychiatrists to market Gabitril or Provigil since psychiatrist are not using either medication for a FDA approved purpose.

52. Yet Cephalon management has instructed its sales representatives to promote and market Gabitril primarily as an off-label medication to psychiatrists for the treatment of anxiety, mood disorder, and depression.

53. To further its off label promotion scheme, Cephalon has engaged in numerous practices that violate FDA regulations prohibiting off label promotions.

54. Cephalon management has encouraged sales representatives to make false statements concerning the efficacy of Gabitril.

Cephalon's Misrepresentations About Gabitril

55. To further its aggressive off-label promotion of Gabitril to psychiatrists, Cephalon conducts training seminars in which the sales representatives are instructed as to how to initiate discussions with psychiatrists for purposes of off-label promotion.

56. At these role playing training sessions, the sales representations are instructed how to use charts, diagrams, and unapproved written materials for purposes of the off-label promotions.

57. The Cephalon sales representatives are also accompanied by their managers and instructed as to what misrepresentations to make about Gabitril.

58. For example the sales representatives are instructed to take specific recommendations for dosing requirements for the use of Gabitril in the treatment for depression when in fact there is no known dosing regimen for Gabitril in the treatment of depression.

59. Some physicians have been so offended by the Cephalon sales representatives that they have asked the representatives to leave the office and have threatened to report Cephalon to the FDA for illegal promotion of medications.

60. The sales representatives are also instructed to take with them on sales calls a document referred to as the "Gruner Report", which is a small case study performed by Dr. Gruner on the use of Gabitril to treat depression. Gruner is a psychiatrist that has received honoria from Cephalon in exchange for speaking on the benefits of Gabitril.

61. The sales representatives are also encouraged to take with them on calls to psychiatrists articles about Gabitril taken from the internet, included among these is an article by Gregory Krauss, M.D. These internet articles are, of course, not approved by the FDA.

Cephalon Illegal Sampling Practices

62. During their training sessions the sales representatives are also instructed to leave large samples of Gabitril with the psychiatrists for off-label use. The large scale sampling practice is an integral part of Cephalon's off-label promotion campaign.

63. Cephalon's illegal sampling practices has led to its sales representatives leaving huge doses of Gabitril at the offices of psychiatrist even though there is no approved use or known dosage requirements for psychiatrists to use this medication.

Cephalon Illegal use of Honoria

64. Cephalon also encouraged its sales representatives to recruit psychiatrists by paying them honoraria in return for recommending Gabitril to other psychiatrists during speaking engagements.

65. Cephalon's off-label promotional campaigns have been memorialized in numerous business plans, sales representative reviews, and field notes, despite Cephalon's best efforts to disguise its off label promotional activities.

66. Cephalon management has instructed sales representatives, in writing, that their time and money should be spent in marketing Gabitril off-label to psychiatrist. Management has gone so far as to instruct their sales representatives that any time or money spent by sales representatives in marketing Gabitril to physicians other than psychiatrists will be strictly scrutinized.

67. Cephalon's off-label sales and promotional initiatives with Gabitril are part of a pattern in which Cephalon has also engaged with the off-label marketing of Provigil and Actiq.

Gabitril Represents An Immediate Health Risk to the Public

68. The health risks surrounding Gabitril are magnified because Gabitril impacts the central nervous system and it has therefore been known to have serious side effects.

69. Because ***no FDA approved studies*** have ever been performed on Gabitril for use in the treatment of anxiety, mood disorder, or pain, there are no indications whatsoever as to what the proper dosage requirements would be for such treatment. The sales representatives therefore have no basis to recommend the appropriate dosages for such use.

70. Despite the lack of guidance in dosage requirements for the use of Gabitril for the treatment of depression, mood disorder and anxiety, Cephalon management is instructing sales representatives to **recommend the dosing regimen** taken **from unapproved tests** that have been reported on the internet and elsewhere.

71. There have also been no determinations, preliminary or otherwise, by the FDA or any other regulatory agency as to what indications should be present before treating patients with

Gabitril, which acts upon the central nervous system, for conditions as common as anxiety and mood disorder.

72. The Cephalon sales force is therefore promoting Gabitril for use in patients with anxiety and mood disorder with no guidance as to dosage requirements or presenting symptoms before Gabitril is prescribed.

73. In fact, Cephalon management is also insisting that Cephalon sales representatives promote the use of Gabitril off label to pediatric patients, despite the lack of guidance by the FDA or approved medical studies.

74. Nonetheless, Cephalon's marketing strategy to focus upon psychiatrists has been largely successful, boosting Gabitril's sales and use for off-label purposes and leading to sales well beyond those for which it has been approved by the FDA (as an anti-convulsant in the treatment of partial seizures).

Paccione's Objection to the "Off-Label Promotion of Gabitril

75. The Cephalon sales force was generally uneasy about the aggressive marketing of Provigil, Gabitril, and Actiq for off-label purposes.

76. Paccione did not market Actiq since she was in the CNS Division and Actiq was marketed by the Pain Division. Cephalon management did insist that the CNS sales representatives, including Paccione, aggressively market Provigil "off-label" beyond its FDA approved use of treating fatigue related to narcolepsy.

77. Gabitril has never been formally tested outside its narrow use as an anti-convulsant for the treatment of partial seizures. Once Cephalon acquired the rights to Gabitril from Abbott in 2001, Paccione became increasingly uneasy about the manner in which Cephalon management was instructing her to market the drug.

78. It is Paccione's understanding that, because Gabitril impacts the central nervous system, its side effects are much more pronounced than Provigil.

79. Thus Paccione was very uncomfortable marketing Gabitril to pediatric patients and to psychiatrists for mood disorder, anxiety or pain. She was particularly uncomfortable discussing dosage requirements with physicians.

80. Yet, beginning in 2001, Cephalon management, particularly Paccione's direct supervisor, Jeff Aromondo, instructed Paccione to concentrate her marketing and promotion efforts solely on psychiatrists, even though psychiatrists had no known use for the FDA approved purpose of Gabitril. When Paccione expressed her concerns about such a marketing and promotion emphasis, she was repeatedly criticized in her written Performance Appraisals beginning in 2001.

81. For instance, in her written performance appraisals Paccione is criticized for not being aggressive enough in "identifying and developing new accounts in psychiatry", even though Cephalon management well knew that such "off-label" marketing and promoting was illegal.

82. She was also criticized in her written Performance Appraisals for not embracing the "GABA mechanism of action story" and not being "persuasive" enough when engaging in "off-label" marketing to psychiatrists. Paccione is also criticized for not instructing psychiatrists that the maximum dosage for various "off-label" uses is 32-56 milligrams, when in fact the FDA has not provided any dosage requirements for such purposes because the medications have never been approved for those purposes.

83. Paccione was instructed, again in writing, to become more familiar with "the concept of why Gabitril may be appropriate versus a benzodiazepine, another completely off-label use of Gabitril for which there have been no studies performed and for which there has been no FDA approval sought.

84. Paccione, again in writing, is instructed that persuading physicians to use Gabitril as a substitute for benzodiazipines when treating anxiety "is an area of incredible opportunity for potential sales that needs to be understood if you are going **to drive the sales as required."**

85. Paccione was also instructed by Aromondo to write her field notes in such a way as to ***"disguise" the off-label marketing***. In fact, it was a common discussion amongst sales representatives as to how they should write field notes disguising their marketing and promotion efforts.

86. Paccione's immediate supervisor, Jeffrey Aromondo, accompanied her on numerous sales calls in which he reviewed and critiqued her use of the non-FDA approved written materials, including the Gruner report and various internet articles on Gabitril.

87. Aromondo insisted that Paccione bring these articles on sales calls and also insisted that Paccione more aggressively insist upon leaving large samples with psychiatrists as part of Cephalon's off-label promotions.

88 In performance reviews, Aromondo directly criticizes Paccione for not leaving enough Gabitril samples with psychiatrists and encourages her to leave more sales as part of the off-label promotions.

89. Numerous Cephalon district managers in both sales divisions instructed their sales representatives to simply write the notation "product reminder" in their field notes so that the FDA would not discover evidence of "off-label" marketing if the FDA ever reviewed the notes.

90. Plaintiff was terminated without any severance package on January 14, 2003, despite the fact that she had been with the company since its beginnings, and had consistently provided among the highest sales in the country.

As a result of the foregoing events, Plaintiff has suffered financial harm and pain and suffering.

COUNT I
(Violation of False Claims Act – 31 U.S.C. S3729 ET SEQ.)

91. Plaintiffs incorporate by reference and re-allege Paragraphs 1-90 as if fully set forth herein. This Count is brought by Paccione in the name of the United States under the *qui tam* provisions of 31 U.S.C. §3730 for defendants' violation of 31 U.S.C. §3729 *et seq.*

92. By virtue of the above-described acts, among others, defendant Cephalon knowingly caused to be presented false or fraudulent claims for payment or approval, and possibly continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the United States.

93. The amounts of the false or fraudulent claims to the United States were material. Plaintiffs United States, being unaware of the falsity of the claims and/or statements made by defendant, and in reliance on the accuracy thereof paid and may continue to pay defendant for improperly switched prescriptions.

WHEREFORE, Plaintiff respectfully requests the Court enter judgment against Defendant Cephalon and award Plaintiff appropriate damages, together with attorneys fees and costs, and such other relief as the Court deems just and equitable.

COUNT II

(Violation of False Claims Act – 31 U.S.C. S3730(h))

94. Paragraphs 1 through 93 of this Complaint are incorporated by reference as though fully set forth herein.

95. Defendant Cephalon, acting through its duly authorized agents, violated the Federal False Claims Act, section 3730(h), by terminating Paccione's employment at Cephalon in retaliation for disclosing her concerns and objections to her immediate supervisor about the use of the illegal "off label" marketing of Gabitril which constituted a practice of Defendant Pfizer that violated the Food, Drug and Cosmetics Act, 21 U.S.C. §§ 301 *et seq*. and applicable regulations. Furthermore, Pfizer's violation of that Act and related regulations created and presents a substantial and specific danger to the public health or safety.

96. As a result of her retaliatory discharge by Defendant Cephalon, Plaintiff Paccione has suffered actual damages in the form of lost wages, fringe benefits, stock options and other employment related benefits and compensation.

97. In addition to compensatory damages, Plaintiff also demands payment of attorney's fees, costs and disbursements.

WHEREFORE, Plaintiff Lucia Paccione respectfully requests the Court enter judgment against Defendant Cephalon and award Plaintiff Paccione compensatory damages, together with attorneys fees and costs, and such other relief as the Court deems just and equitable.

Respectfully submitted,

United States of America ex rel.
Lucia Paccione

By: _____
Attorney for the Plaintiff

Date: 11/13/03

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